B1 cancel.

c) optionally other excipients; and

wherein the active ingredient is present in an amount of 80 to 95% by weight of the total composition.--

Amend claim 4 as follows:

B2

--4. (amended) Compositions as claimed in claim 1, wherein the hydrophilic matrix consists of hydrogel-forming compounds.—

Cancel claim 10.

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claim 10 has been canceled. The recitation of claim 10 may now be found in amended claim 1. Claim 4 has been amended to more particularly point out and distinctly claim the present invention.

In the outstanding Official Action, claim 4 was objected to under 37 CFR §1.75(c) as allegedly being in improper multiple dependent form. In the interest of advancing prosecution, claim 4 has been amended to depend from claim 1. Thus, it is believed that the claimed invention satisfies the requirements of 37 CFR §1.75(c).

In the outstanding Official Action, claims 1-5, 8, 9, and 11 were rejected under 35 USC §102(b) as allegedly being anticipated by AKIYAMA et al. 5,593,690. Claims 1-5, 8, 9, and 11 were also rejected under 35 USC §103(a) as allegedly being obvious in view of AKIYAMA et al. These rejections are traversed.

It is respectfully submitted that AKIYAMA et al. fail to disclose or suggest the claimed invention. The claimed invention relates to a composition comprising two matrices. The matrices comprise a lipophilic inner matrix and an hydrophilic outer matrix. The inner lipophilic matrix consists of substances with melting points below 90°C in which an active ingredient is at least partially inglobated. The two matrices allow for the incorporation of high amounts of active ingredients in the claimed composition and provide for the control and extended dissolution of the active ingredient. Im fact, the active ingredient may be present in the composition in an amount of 80 to 95% by weight of the total composition.

It is believed that the AKIYAMA et al. publication fails to recite each and every recitation of the claimed invention. AKIYAMA et al. disclose that controlled released active substances are dispersed in granules. The active ingredients are in a lipophilic matrix which may be optionally coated with coating agents (see column 6, lines 49-67). AKIYAMA et al. teach that the active ingredient is

present in the granules in an amount ranging from 0.005 to 75% by weight of a total composition.

However, applicants believe that AKIYAMA et al. fail to disclose or suggest the two matrices and the arrangement of the matrices as set forth in the claimed invention. The arrangement of the matrices in the present invention aid in the combined release of an active ingredient via diffusion from a lipophilic matrix.

Applicants also believe that AKIYAMA et al. fail to teach that mesalazine (5-aminosalicyclic acid) may be used as the active ingredient. While AKIYAMA et al. disclose that aspirin (acetylsalicylic acid) can be used in granules, AKIYAMA et al. do not teach that the active ingredient can be mesalazine.

Moreover, AKIYAMA et al. are incapable of providing a controlled release oral pharmaceutical composition comprising 80 to 95% of an active ingredient. In fact, AKIYAMA et al. teach a composition wherein the active ingredient is in an amount much lower than that according to the claimed invention. As noted in the present specification, the claimed composition can contain high amounts of active ingredients. In the case of mesalazine, this is desirable because mesalazine requires high unitary doses (see present specification, page 6, lines 15-20).

Finally, applicants note that the coating of the lipophilic matrix is optional according to AKIYAMA et al.

and may indifferently consist of either lipophilic substances or hydrophilic substances. As a result, applicants believe that AKIYAMA et al. do not teach the characteristics of the two matrices of the claimed invention.

As AKIYAMA et al. fail to disclose or suggest each and every recitation of the claimed invention, it is believed that AKIYAMA et al. fail to anticipate or render obvious the claimed invention.

In the outstanding Official Action, claims 1-11 were rejected under 35 USC §103(a) as allegedly being unpatentable over FRANCO et al. This rejection is respectfully traversed.

FRANCO et al. disclose oral compositions comprising a core containing an active ingredient coated by a lipophilic layer and a surfactant with HLB ranging from 10 to 16, in amounts from 5 to 20% by weight of the lipophilic material. The core can be in the form of a tablet or capsule. FRANCO et al. disclose immediate and controlled release compositions.

The compositions are based on a "reservoir" system rather than an actual matrix. In other words, the active ingredient is confined within a core which acts as a reservoir from which the active ingredient is released via the erosion of the outer coating.

However, as to the present invention, the active ingredient is dispersed in a lipophilic matrix, not in an isolated core. Thus, the present invention discloses an inner lipophilic matrix and an outer hydrophilic matrix. Applicants believe that FRANCO et al. disclose an inner core in the form of a tablet with an outer lipophilic coating.

As to the magnesium stearate, magnesium stearate is included in the core taught by FRANCO et al. However, the present invention does not require that magnesium stearate be used in the lipophilic matrix. The excipient may be used in the final tabletting step according to its conventional lubricant properties.

Thus, in view of the above, it is believed that FRANCO et al. fail to render obvious the claimed invention.

In the outstanding Official Action, claims 1-9 and 11 were rejected under 35 USC §103(a) as allegedly being unpatentable in view of SANGHVI et al. 5,852,555 and STRAUB et al. 6,395,300. This rejection is respectfully traversed.

Applicants respectfully submit that the SANGHVI et al. publication fails to disclose a system containing two separate matrices. The SANGHVI et al. publication merely discloses formulations obtained by mixing together hydrophilic and lipophilic substances into a single matrix. The highest amount that the active ingredient may be incorporated into the composition taught by SANGHVI et al.

is 40%. As noted above, this is below the actual content of the compositions according to the present invention (80-95%).

In an effort to remedy the deficiencies of SANGHVI et al., the Official Action cites STRAUB et al. However, it is believed that STRAUB et al. fail to remedy the deficiencies of SANGHVI et al. Applicants respectfully submit that the proposed combination of STRAUB et al. with SANGHVI et al. would not have led one of ordinary skill in the art to the claimed invention. While the publications might teach the advantageous results of using a lipophilic matrix, the publications fail to disclose or suggest a composition comprising a combination of two separate matrices. In fact, there is no mention or suggestion of a composition utilizing different control mechanisms.

As noted in the present specification, the control mechanisms of the present invention help the claimed composition in incorporating large amounts of active ingredient. As a result, applicants believe that one of ordinary skill in the art would not be able to obtain the claimed invention based on the proposed combination of SANGHVI et al. and STRAUB et al.

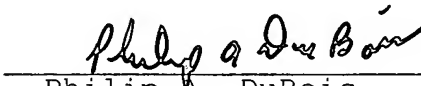
In view of the above, it is respectfully submitted that the proposed combination of SANGHVI et al. in view of STRAUB et al. fails to render obvious the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 1-9, and 11, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

YOUNG & THOMPSON

By 

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April 29, 2003

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 1 was amended as follows:

--1. (amended) Controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, comprising:

a) an inner lipophilic matrix consisting of substances with melting points below 90°C in which the active ingredient is at least partly inglobated;

b) an outer hydrophilic matrix in which the lipophilic matrix is dispersed;

c) optionally other excipients; and

wherein the active ingredient is present in an amount of 80 to 95% by weight of the total composition.--

Claim 4 was amended as follows:

--4. (amended) Compositions as claimed in [any one of the above claims] claim 1, wherein the hydrophilic matrix consists of hydrogel-forming compounds.--